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Application No. 10/511,433
Amendment dated April 4, 2006
Reply to Office Action of January 4, 2006

REMARKS

Claims 1 to 17 are pending in the application.

With respect to the objection to the drawings, the replacement sheet of drawings (including Figures 1A, 1B and 1C) submitted herewith is believed to overcome the Examiner's objections. In addition, the specification has been amended both in the sections entitled "Brief description of the drawings" on page 5, and in Example I, first paragraph (page 9), in order to harmonize the text of the application with the new drawings.

Claims 18 to 26 have been withdrawn as the result of an earlier restriction requirement.

The Applicant has corrected the informalities that were noted by the Examiner regarding claims 1 and 3. The Examiner also alleged that claim 9 was failing to further limit the subject matter of claim 1. Claim 9 has been amended in accordance with the Examiner's suggestion.

The Examiner rejected claims 1 and 16 for being indefinite, alleging that the expression "continuous living tissue construct" created a confusion as whether the adjective "continuous" was applying to the life of the tissue construct or to the spatial configuration of the tissue construct. The Applicant would like to point the Examiner's attention to page 2, lines 12-13, of the present application, where it is clearly stated that "One object of the present invention is to provide a method for assembling living tissue sheets for forming a continuous tissue construct...". For purpose of clarity, the Applicant agrees to amend claims 1 and 16 so as they now refer to a "living tissue construct of a continuous form". The rejection is overcome by such an amendment.

With respect to the rejection of claims 1 and 3 for indefiniteness for the use of the expression "edge contact", reconsideration by the Examiner is respectfully requested on the

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following grounds. The tissues of the present application are clearly defined throughout the application as being tissue sheets. The Applicant agrees that since tissue sheets are formed of three-dimensional cells, those tissue sheets cannot be considered as being two-dimensional objects. However, sheets are generally recognized as being nearly two-dimensional, traditionally having only two functionally working surfaces, or faces, the front and the back (e.g. a sheet of paper). The "side surfaces", connecting the front and the back of a sheet, are not adapted to be as functionally working as the front and the back of a sheet, and are therefore traditionally not considered as being surfaces but rather edges. Such a knowledge is not specific to any art in itself, but is instead of common general knowledge. The Applicant therefore submits that any person, not just persons of the art, would understand that contacting two edges of two sheets would imply putting the two sheets side-by-side and not one on top of the other. This latter disposition would rather be described as "stacking the sheets" or "contacting the surfaces (or faces) of the sheets". Consequently, the Applicant respectfully request that this rejection be removed.

Claims 3 and 4 have been rejected for allegedly being unclear. Amended claim 3 submitted herewith overcomes this rejection.

Claim 10 has been rejected for allegedly lacking sufficient antecedent basis. New amended claim 10 submitted herewith overcomes this rejection.

Claims 13 and 14 have been rejected for allegedly being unclear. New amended claim 13 submitted herewith overcomes this rejection.

Claim 15 has been rejected for allegedly being unclear, and for insufficient antecedent basis. New amended claim 15 submitted herewith, now dependent on claim 13, overcomes this rejection.

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Claim 16 has been rejected for allegedly being indefinite for its use of the term "rolling". New amended claim 16 submitted herewith overcomes this rejection by specifying that the living tissue construct is rolled around a tubular support. The support for such an amendment can be found on page 11, lines 10-14, of the present application.

Claim 17 has been rejected by the Examiner for claiming the creation of a blood vessel. New amended claim 17 overcomes this rejection.

With respect to the rejection of claims 1, 2, 5-11 and 15-17 under 35 USC § 102 as being anticipated by L'Heureux *et al.* (FASEB, 1998), reconsideration by the Examiner is respectfully requested on the following grounds. In the present application, the contact between two cell populations is carried out by contacting their respective edges to eventually form a unique and living continuous tissue construct, which is in fact a living tissue sheet made of two edge-assembled cell populations. The resulting living continuous tissue construct is therefore formed in only one step, and can further be used or manipulated in order to form a tube or an artificial blood vessel in only one step, that one step being the rolling of the living continuous tissue construct around a tubular support in a single operation to give a tubular tissue construct. By opposition, L'Heureux describes a method in which a first cell sheet is wrapped around an inert tubular support to produce a first cell layer, which is then covered by a second cell sheet, separately manipulated to finally form a tubular tissue. The method of L'Heureux, in addition of being performed in two distinct steps, causes overlapping of portions of each one of the sheets over the other, and therefore creates imperfections in the tubular tissue. The method of the present application totally avoids such overlapping of the border of living tissue sheets or cell sheets when preparing a living continuous tissue construct. Moreover, L'Heureux never mentions the edges relationship between two cell populations, nor the method to obtain such relationship is disclosed.

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Furthermore, the contact between the two cell sheets occurs in L'Heureux while the cells are removed from their culture support, while the contact between the two cell sheets in the present application occurs during the cell culture. Consequently, the Applicant respectfully submits that L'Heureux does not anticipate or describe the methods of claims 1, 2, 5-11 and 15-17 of the present application.

With respect to the rejection of claims 1, 2, 5, 6, 9-11 and 13-15 under 35 USC § 102 as being anticipated by Quinn *et al.* (US Patent 5,750,329), reconsideration by the Examiner is respectfully requested on the following grounds. The basic feature of the reference by Quinn is the seeding of cells onto the surface of artificial microporous membranes, while in the present application, the cells produce their own matrix or are seeded into a gel of collagen. Moreover, the membrane used by Quinn stays present in the resulting tissue construct, whereas our separator (which can be a membrane, but can also be any other separating mean) is not part of the resulting tissue construct. Furthermore, similarly to the reference of L'Heureux, the contact between two tissue sheets occurs directly from stacking of one sheet over the other, via the passage throughout the membrane, while the contact of two tissue sheets in the present application occur by assembly of the edges of two tissue sheets. In consequence, the Applicant respectfully submits that Quinn does not anticipate or describe the methods of claims 1, 2, 5, 6, 9-11 and 13-15 of the present application.

With respect to the rejection of claims 3 and 4 under 35 USC § 103 as being anticipated by Quinn *et al.* (US Patent 5,750,329), reconsideration by the Examiner is respectfully requested on the following grounds. In addition of teaching a completely different method (the stacking of tissue sheets one on top of the other instead of the edge assembly of two side-by-side tissue sheets like in the present application), and providing a completely different product (a tissue construct that still possess a membrane "sandwiched"

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between two tissue sheets, while products produced by the methods of the present application do not contain any material other than the tissue sheets of interest), Quinn further states that experiments should be performed before one tries to use these teachings in a different context than the one explicitly disclosed. On column 9, lines 23-25, Quinn warns that "certain systems may require optimization studies to identify the best matrix material to include in a particular type of artificial organ system." Hence, the technician in the art seeking to perform the method of the present application not only would not have had any motivation in attempting to use a different method producing a different product than those of the present application, but would have been discouraged by Quinn himself of doing so since Quinn clearly states that experimentation should be performed in order to use the method it teaches for any different application. In consequence, the Applicant is respectfully submitting that the rejection of claims 3 and 4 under 35 USC § 103 be declared moot.

With respect to the rejection of claim 12 under 35 USC § 103 as being unpatentable over L'Heureux (FASEB, 1998) and/or Quinn *et al.* (US Patent 5,750,329), each in view of Lanza *et al.* (US Patent 6,808,704), reconsideration by the Examiner is respectfully requested on the following grounds. As stated previously, the methods, and products produced by those methods, of both L'Heureux and Quinn are so different than those of the present application that it makes no doubt to the Applicant that the person of the art would not have had any motivation in trying to apply those teachings to achieve the methods, and products produced by those methods, of the present application. Briefly, L'Heureux teaches a method in which two tissue sheets are stacked one over the other, in more than one step, and can create a tubular tissue composed of more than one tissue sheet in which there is an overlapping of portions of each one of the sheets over the other, therefore creating imperfections in the tubular tissue. Quinn also teaches the stacking of two tissue sheets by using a microporous

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membrane, instead of their edge assembly like in the present application, and by doing so, is creating a tissue which still retains the microporous membrane as a permanent component of the tissue constructed. The person in the art, lacking the crucial basics to achieved the methods of the present application, and the products produced by those methods, would not have any motivation whatsoever in trying to relate the teachings of Lanza to those of either L'Heureux or Quinn, or both. Consequently, the Applicant respectfully submits that neither L'Heureux or Quinn, taken alone or in combination in the light of Lanza, anticipate, describe or even suggest the methods of claim 12 of the present application.

The Applicants submit that no new matter has been added by the present amcnments.

It is submitted, therefore, that the claims are in condition for allowance. Reconsideration of the Examiner's rejections is respectfully requested. Allowance of claims 1 to 17 at an early date is solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

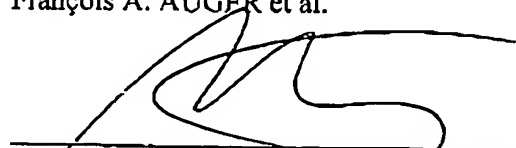
Respectfully submitted,

François A. AUGER et al.

By:

April 4, 2006

Date

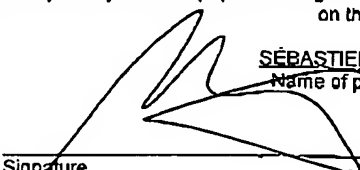

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Encl. - Replacement Drawing(s)

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Signature	<u>April 4, 2006</u> Date

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AMENDMENTS TO THE DRAWINGS

Please replace the sheet of drawings presently on file with the new sheet of drawings submitted herewith.

Attachment: Replacement Drawings 1A, 1B and 1C.